

In the Office Action, the Examiner objected to the specification to the extent that the phrase "bone flap 26" on page 7, line 3 should be --bone flap 36--. In response, Applicants have amended the specification as suggested. No new matter is believed to have been added.

Claims 1, 5-6, and 8-10 were rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,800,436 to Lerch ("Lerch"). Lerch is directed to a device for postoperative fixation back into the cranium of a plug of bone removed therefrom during a surgical operation. The Office Action states:

Lerch discloses a clamp (Figure 4) with a first clamping member 21, a second clamping member 22 and a pin or extension member 11 with a head 111 to prevent the first clamping member 21 from sliding off extension member 11 (col. 1, lines 42-51, col. 2 lines 50-64 and Figure 1). Lerch further discloses that excess length of extension member 11 is cut off after utilizing a tool of the type employed to fasten blind rivets (col. 3, lines 34-43). A blind rivet type device inherently deforms to plug opening 221 in first clamping member 21.

Applicants' invention, as presented in amended independent claim 1, is directed to a cranial flap clamp for fixing a bone flap to a skull comprising: a first clamping member having inner and outer surfaces, at least a portion of the inner surface positionable against inferior surfaces of the bone flap and skull; an extension member extending from the first clamping member and configured and dimensioned to fit between the bone flap and the skull; a second clamping member having inner and outer surfaces and an opening through the inner and outer surfaces for slidably receiving the extension member, with at least a portion of the inner surface positionable against superior surfaces of the bone flap and skull, wherein movement of at least one of the first and second clamping members from a first position with the second clamping member distal to the first clamping member to a second position with the second clamping member proximal to the first clamping member urges the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and urges the inner surface of the second clamping member against the superior surfaces of the bone flap and skull; and an integrally formed stop on the extension member provided by mechanical deformation of the extension member at a surgeon selected location along its length and adjacent the outer surface of the second clamping member when the first and second clamping members are in the second position to secure the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and the inner surface of the second clamping member against the superior surfaces of the bone flap and skull.

Lerch is understood to be silent at least with respect to an integrally formed stop on the extension member provided by mechanical deformation of the extension member at a surgeon selected location along its length and adjacent the outer surface of the second clamping member, as recited in amended independent claim 1. Although the Office Action cites to col. 3, lines 34-43 of the Lerch specification, neither this disclosure nor FIGS. 5 and 6 referenced therein show such a construction. According to Lerch, FIG. 5 illustrates how the device "can be employed" while FIG. 6 is a section along the line VI-VI in FIG. 5. (Lerch, Col. 2, lines 40-42). The Lerch specification states:

[A] tool forces outer disks 22 and inner disks 21 together in the direction indicated by arrow B in FIG. 6 until the teeth on each disk bite into the tissue of the plug and of the residual cranium, securing the two together. The section of each shaft extending out beyond the outer disk is now trimmed off. The shaft can alternatively be threaded, and the disks forced together over the threads until the teeth bite into the tissue.

(*Id.*, Col. 3, lines 35-42). Furthermore, although the Office Action states that "[a] blind rivet type device inherently deforms to plug opening 221 in first clamping member 21," the shaft 112 of pin 11 as shown in FIG. 6 of Lerch is understood to lack any such deformation. Allowance of claims 1, 5-6, and 8-10 is respectfully requested.

Claim 7 was rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Lerch. The Office Action states that "Lerch does not specifically disclose an enlarged portion near the inner surface of first clamping member 21" but that "it would have been obvious to one of ordinary skill in the art to provide an enlarged portion near the inner surface of first clamping member 21 since it is well known in the art to fix clamping members on a tubular shaft to prevent their movement on the shaft."

As noted with respect to the previous rejection under § 102, Lerch does not disclose an integrally formed stop on the extension member provided by mechanical deformation of the extension member at a surgeon selected location along its length and adjacent the outer surface of the second clamping member. Thus, because dependent claim 7 depends from amended independent claim 1, it is submitted that this claim is patentable not only because of the patentability of the independent claim from which it depends, but also for the totality of features recited therein.

In view of the foregoing, it is believed that all pending claims are in condition for allowance, which is respectfully requested. If the Examiner does not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and accelerate the eventual allowance of the claims.

A fee is believed to be due for the presentation of new claims, and a Fee Transmittal Sheet is submitted concurrently herewith. A fee for an extension of time also is believed to be due for this submission and a petition for extension of time is submitted concurrently herewith. Should any additional fees be required, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

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Enclosures

**EXHIBIT A - MARKED-UP VERSION OF PARAGRAPH
OF SPECIFICATION IN AMENDMENT FILED JUNE 30, 2003**

Amend the paragraph of the specification at page 6, line 32 to page 7, line 6, as follows:

In order to minimize the risk of injury to the brain during implantation of cranial flap clamp 10, inner surfaces 18, 28 of first and second clamping members 12, 14 do not have teeth or similar surface features. In other words, inner surfaces 18, 28 are substantially smooth. If the inner surfaces of either or both of first and second clamping members 12, 14 are concave, then movement from the first position to the second position will tend to flatten out the inner surfaces so that more surface area contacts the inferior and/or superior surfaces of bone flap [26] 36 and skull 38. In order to enhance this effect, either or both of first and second clamping member can be provided with radial cutouts. For example, FIG. 3 shows that second clamping member 14 has a plurality of radial cutouts 50 extending radially from opening 32.

**EXHIBIT C - MARKED-UP VERSION OF AMENDED CLAIMS AND
NEW CLAIMS PRESENTED IN AMENDMENT FILED JUNE 30, 2003**

1. (Amended) A cranial flap clamp for fixing a bone flap to a skull comprising:
a first clamping member having inner and outer surfaces, at least a portion of the inner surface positionable against inferior surfaces of the bone flap and skull;
an extension member extending from the first clamping member and configured and dimensioned to fit between the bone flap and the skull;
a second clamping member having inner and outer surfaces and an opening through the inner and outer surfaces for slidably receiving the extension member, with at least a portion of the inner surface positionable against superior surfaces of the bone flap and skull,

wherein movement of at least one of the first and second clamping members from a first position with the second clamping member distal to the first clamping member to a second position with the second clamping member proximal to the first clamping member urges the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and urges the inner surface of the second clamping member against the superior surfaces of the bone flap and skull; and

[a] an integrally formed stop on the extension member provided by mechanical deformation of the extension member at a surgeon selected location along its length and adjacent the outer surface of the second clamping member when the first and second clamping members are in the second position to secure the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and the inner surface of the second clamping member against the superior surfaces of the bone flap and skull.

2. (Amended) [The cranial flap clamp of claim 1] A cranial flap clamp for fixing a bone flap to a skull comprising:
a first clamping member having inner and outer surfaces, at least a portion of the inner surface positionable against inferior surfaces of the bone flap and skull;
an extension member extending from the first clamping member and configured and dimensioned to fit between the bone flap and the skull;

a second clamping member having inner and outer surfaces and an opening through the inner and outer surfaces for slidably receiving the extension member, with at least a portion of the inner surface positionable against superior surfaces of the bone flap and skull,

wherein movement of at least one of the first and second clamping members from a first position with the second clamping member distal to the first clamping member to a second position with the second clamping member proximal to the first clamping member urges the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and urges the inner surface of the second clamping member against the superior surfaces of the bone flap and skull; and

a stop provided by mechanical deformation of the extension member at a surgeon selected location along its length and adjacent the outer surface of the second clamping member when the first and second clamping members are in the second position to secure the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and the inner surface of the second clamping member against the superior surfaces of the bone flap and skull;

wherein the inner surfaces of the first and second clamping members are substantially smooth.

11. (Amended) [The cranial flap clamp of claim 1] A cranial flap clamp for fixing a bone flap to a skull comprising:

a first clamping member having inner and outer surfaces, at least a portion of the inner surface positionable against inferior surfaces of the bone flap and skull;

an extension member extending from the first clamping member and configured and dimensioned to fit between the bone flap and the skull;

a second clamping member having inner and outer surfaces and an opening through the inner and outer surfaces for slidably receiving the extension member, with at least a portion of the inner surface positionable against superior surfaces of the bone flap and skull,

wherein movement of at least one of the first and second clamping members from a first position with the second clamping member distal to the first clamping member to a second position with the second clamping member proximal to the first clamping member urges the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and urges the inner surface of the second clamping member against the superior surfaces of the bone flap and skull; and

a stop provided by mechanical deformation of the extension member at a surgeon selected location along its length and adjacent the outer surface of the second clamping member when the first and second clamping members are in the second position to secure the inner surface of the first clamping member against the inferior surfaces of the bone flap and skull and the inner surface of the second clamping member against the superior surfaces of the bone flap and skull;

wherein the extension member is a ribbon and the opening of the second clamping member has a rectangular shape.

27. (New) A cranial flap clamp for fixing a bone flap to a skull comprising:
a first clamping member positionable against inferior surfaces of the bone flap and skull;

an extension member extending from the first clamping member and configured and dimensioned to extend between the bone flap and the skull;

a second clamping member positionable against superior surfaces of the bone flap and skull and comprising an opening in which a portion of the extension member is disposed; and

an integrally formed stop on the extension member for limiting movement of the second clamping member when the first clamping member abuts the inferior surfaces and the second clamping member abuts the superior surfaces.

28. (New) The cranial flap clamp of claim 27, wherein surfaces of the first and second clamping members that abut the surfaces of the bone flap and skull are substantially smooth.

29. (New) The cranial flap clamp of claim 27, wherein the first and second clamping members each further comprise a disk shape.

30. (New) The cranial flap clamp of claim 29, wherein the second clamping member further comprises a plurality of cutouts oriented radially with respect to the opening.

31. (New) The cranial flap clamp of claim 27, wherein the extension member comprises a tube and the stop comprises a crimp in the tube.

32. (New) The cranial flap clamp of claim 31, wherein the opening has a substantially circular shape that is smaller than the crimp.

33. (New) The cranial flap clamp of claim 27, further comprising a head disposed on the extension member proximate the first clamping member.

34. (New) The cranial flap clamp of claim 27, wherein the first clamping member comprises a bore for receiving the extension member.

35. (New) The cranial flap clamp of claim 27, wherein the opening comprises a countersink and the stop is disposed substantially within the countersink.

36. (New) The cranial flap clamp of claim 27, wherein the first and second clamping members each comprise an arcuate outer edge.

37. (New) The cranial flap clamp of claim 27, wherein the extension member comprises a ribbon.

38. (New) The cranial flap clamp of claim 37, wherein the stop comprises a twisted portion of the ribbon.

39. (New) The cranial flap clamp of claim 27, wherein the stop comprises a twisted portion of the extension member.

40. (New) The cranial flap clamp of claim 27, wherein the second clamping member comprises a recessed area proximate the opening.

41. (New) The cranial flap clamp of claim 40, wherein the stop is received in the recessed area.

42. (New) The cranial flap clamp of claim 40, wherein the recessed area has a width that increases from a center of the opening, a depth that increases from the center of the opening, and an edge that forms a cutting surface.

43. (New) The cranial flap clamp of claim 27, wherein the extension member is integral with the first clamping member.

44. (New) The cranial flap clamp of claim 27, wherein the second clamping member comprises at least one fastener hole for receiving a fastener.

45. (New) A cranial flap clamp for fixing a bone flap to a skull comprising:
a first clamping member;
an extension member extending from the first clamping member;
a second clamping member comprising an opening in which a portion of the extension member is disposed; and
an integrally formed stop on the extension member for limiting movement of the second clamping member on the extension member, the stop being disposed proximate an end of the extension member.

46. (New) The cranial flap clamp of claim 45, wherein the extension member is integral with the first clamping member.

47. (New) The cranial flap clamp of claim 45, wherein the stop comprises a crimped portion of the extension member.

48. (New) The cranial flap clamp of claim 45, wherein the stop comprises a twisted portion of the extension member.

49. (New) The cranial flap clamp of claim 45, wherein opposing surfaces of the first and second clamping members are substantially smooth.